REMARKS

Claims 1-26 are pending. Claims 1 and 23 are currently amended. No new matter has been introduced by virtue of the amendments made herein. Accordingly, Applicants respectfully request entry of the amendments made herein.

In view of the amendments made herein and the remarks below, Applicants respectfully request reconsideration and withdrawal of the rejections set forth in the October 23, 2007 Office Action.

Rejections In View Of Holman

Claims 1-4, 8-9, 13-20 and 24-26 have been finally rejected under 35 USC § 102(e) as allegedly being anticipated by United States Patent No. 6,277,875 (hereinafter "Holman"). In addition, Claims 1-22 and 24-26 have been finally rejected under 35 USC § 103(a) as allegedly being obvious in view of Holman (alone).

As set forth in the Office Action, the rejections in view of Holman have been maintained because: (1) allegedly, the Applicants have not shown that the formulations disclosed in Holman are immediate release formulations; and (2) allegedly, the Applicants have not shown that the starch disclosed in the Holman formulations would not have the claimed tensile strength limitation. For the reasons that follow, Applicants respectfully traverse these rejections.

First, Applicants have amended the claims – by introducing the term "sustained release" into the body of the claims – in an effort to more clearly describe the claimed invention as a *sustained-release* pharmaceutical composition of pramipexole. Thus, the present amendment clearly distinguishes the claimed invention from Holman – which discloses the use of dopamine D_2/D_3 receptor agonists for the treatment of fibromyalgia, but fails to disclose sustained-release formulations of such agonists. More specifically, the particular formulations disclosed in Holman – namely, MIRAPEX® (pramipexole) and REQUIP® (ropinirole) — are *not* sustained-release formulations. Indeed, in describing the use of both MIRAPEX® (pramipexole) and REQUIP® (ropinirole) to treat fibromyalgia, Holman cites to the relevant portions of the *Physicians' Desk Reference* ("the PDR"). The PDR describes both MIRAPEX® and REQUIP® as immediate release drugs. *See* PDR, 54th Ed., at 2468 ("Pramipexole is rapidly absorbed, reaching peak concentrations in approximately 2 hours"); and at 3037 ("Ropinirole is rapidly absorbed after oral administration, reaching peak concentration in approximately 1-2 hours."). One having

ordinary skill in the art would understand from the above that both MIRAPEX® and REQUIP® are immediate release drugs. Holman contains no other specific examples of dopamine agonist formulations; nor does it contain any general description of any sustained-release dopamine agonist compositions. Consequently, Holman cannot anticipate a sustained-release pramipexole composition. Thus, the rejection should be withdrawn.

Second, the Office Action takes issue with the Applicants' attempt to demonstrate that different lots or samples of pregelatinized starches can have varying tensile strengths. In particular, the Office Action states that "any reference with [a pregelatinized starch] in a tablet form will anticipate the Applicants' claims." (See Office Action, p. 3). In addition, the Office Action "takes this [required tensile] strength to be an ***inherent*** property of any pre-gelatinized starch absent any physical limitations that would preclude certain starches." (see Office Action, p. 6). However, for the tensile strength requirement to be considered an inherent property of the starch, there must be some evidence to suggest that each and every starch will exhibit that same tensile strength. In view of the evidence that the Applicants pointed to in their response to the first Office Action, that is simply untenable. Rather, the evidence suggested the opposite – i.e., that tensile strength can vary among starch samples. Indeed, Applicants pointed to evidence contained the present application demonstrating that different starches, and indeed, ***different lots of the same starches***, can have differing tensile strengths. Accordingly, there is no basis for the assumption that the tensile strength value is inherent in any starch absent some physical limitation that would preclude certain starches. Consequently, Applicants respectfully submit that the 102(e) rejection based on Holman should be withdrawn.

Finally, since there is no teaching or suggestion in Holman to either (a) modify the immediate-release pramipexole compositions disclosed therein into sustained-release compositions; or (b) use a starch having the requisite tensile strength, it cannot render the present invention obvious. Consequently, Applicants respectfully request that the 103(a) rejection in view of Holman alone be withdrawn.

Rejections In View Of Patel

Claims 1-4, 8-14, 19-20, 22, 24, and 26 have been finally rejected under 35 USC § 102(e) as allegedly being anticipated by United States Patent Application Publication No. U.S. 2003/01800352) (hereinafter "Patel"). Likewise, Claims 1-26 have been rejected as allegedly being obvious under 35 U.S.C. §103(a) in view of Patel (alone). As with the rejections over Holman, the Office Action alleges that the pregelatinized starch in Patel

would inherently meet the tensile strength limitation of the present invention. But as previously demonstrated, Patel's disclosure, in general, of a pregelatinized starch is not an inherent disclosure of the claimed tensile strength limitation of the starches used in the presently claimed invention because previous evidence suggests that different pregelatinized starches will have different tensile strengths. Consequently, because Patel fails to teach, suggest, or disclose the use of a starch having a tensile strength of at least 0.15 kN cm^{-2}, Applicants respectfully submit that the rejections based on Patel should be withdrawn.

Rejection Under 35 USC § 103(a)

Claims 1-26 have been finally rejected as allegedly being obvious under 35 U.S.C. §103(a) in view of Holman in view of Khan (U.S. Pat. No. 5,656,296) and Petrus (WO 00/59477) and in further view of Michaud (EP 0933079). In response, the Applicants submit that the combination of Khan, Petrus and Michaud with Holman does not cure the deficiency of Holman as set forth above – i.e., that Holman (and Patel, for that matter) fail to teach or suggest sustained-release pramipexole compositions containing a starch having a tensile strength of about 0.15 kN cm^{-2}. In this regard, the Office Action relies solely on Michaud in an effort to establish that "compressed formulations comprising pregelatinized starch within Applicants' claimed tensile strength range were already known in the art." (Office Action at p. 7).

Assuming, for the sake of argument only, that Michaud does disclose the use of high-tensile strength starches for use in tablets, such disclosure would still be insufficient to render the presently claimed invention obvious. First, Michaud is directed to tablets that are capable of *rapid disintegration* in an aqueous medium – which is in direct contrast to the *sustained-release* compositions of the present invention. Accordingly, one having ordinary skill in the art would not apply the *rapidly-disintegrating* tablets of Michaud with the *immediate-release* MIRAPEX® composition of Holman and ***reasonably expect*** to arrive at the *sustained-release* compositions of the present invention. Accordingly, Applicants respectfully submit that there is no reasonable expectation of success in applying the teaching of Michaud and Holman to arrive at the instant application.

Second, even if, assuming for the sake of argument only, one were to combine the references, the combination of two immediate-release technologies would not produce a sustained-release composition. Therefore, Applicants respectfully submit that the Office Action has failed to establish a *prima facie* case of obviousness. Accordingly, Applicants submit that claims1-26 are patentable under 35 USC § 103(a), and request withdrawal of the

final rejection.

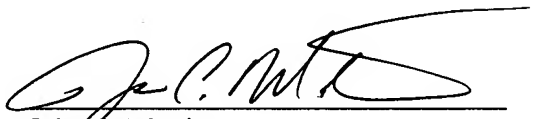
Conclusion

In view of the remarks above and the amendments submitted herein, Applicants respectfully submit that the pending claims are fully allowable, and solicit the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact applicants' undersigned attorneys at the telephone number provided.

The Commissioner is hereby authorized to charge any fees required, including the RCE feed under 37 CFR 1.17(e), or to credit any overpayment to Deposit Account No. 16-1445.

Respectfully submitted,

Dated: April 22, 2008



John C. Martin
Attorney for Applicants
Reg. No. 42,843

Pfizer Inc.
Patent Dept., 5th Floor
150 East 42nd Street
New York, N.Y. 10017-5755
(212) 573-1390